## § 1.809

public of the deposited material will be irrevocably removed upon the granting of the patent.

- (b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:
- (1) Is in writing or other tangible form and dated;
- (2) Contains the name and address of the requesting party and the accession number of the deposit; and
- (3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.
- (c) Upon request made to the Office, the Office will certify whether a deposit has been stated to have been made under conditions which make it available to the public as of the issue date of the patent grant provided the request contains:
- (1) The name and address of the depository:
- (2) The accession number given to the deposit:
- (3) The patent number and issue date of the patent referring to the deposit; and
- (4) The name and address of the requesting party.

## § 1.809 Examination procedures.

- (a) The examiner shall determine pursuant to §1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under the appropriate provision of 35 U.S.C. 112, explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.
- (b) The applicant for patent or patent owner shall reply to a rejection under paragraph (a) of this section by—
- (1) In the case of an applicant for patent, either making an acceptable original, replacement, or supplemental deposit, or assuring the Office in writing

that an acceptable deposit will be made; or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of §1.805, or

- (2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered non-responsive. The rejection will be repeated until either paragraph (b)(1) of this section is satisfied or the examiner is convinced that a deposit is not needed.
- (c) If an application for patent is otherwise in condition for allowance except for a needed deposit and the Office has received a written assurance that an acceptable deposit will be made, applicant will be notified and given a period of time within which the deposit must be made in order to avoid abandonment. This time period is not extendable under §1.136(a) or (b) if set forth in a "Notice of Allowability" or in an Office action having a mail date on or after the mail date of a "Notice of Allowability" (see §1.136(c)).
- (d) For each deposit made pursuant to these regulations, the specification shall contain:
- (1) The accession number for the deposit;
  - (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.
- (e) Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section must be filed before or with the payment of the issue fee (see §1.312).

[54 FR 34880, Aug. 22, 1989, as amended at 66 FR 21092, Apr. 27, 2001]

APPLICATION DISCLOSURES CONTAINING NUCLEOTIDE AND/OR AMINO ACID SE-QUENCES

Source: Sections 1.821 through 1.825 appear at 55 FR 18245, May 1, 1990, unless otherwise noted.